

REMARKS

Applicants have cancelled claims 2, 3, 4, 35 and 39-41 without prejudice and expressly reserve the right to pursue the subject matter of the cancelled claims in one or more subsequently filed applications.

Applicants have rewritten claim 8 in independent form and, further, have amended claims 1, 5, 17-22, 25, 28, 36-38 such that the recited vectors, are derived from clone pFeFV-7. Such amendments are supported at page 5 of the specification.

Further, Applicants have amended claim 1 to incorporate the features of previous claim 2 and amended claim 9 to depend on claim 8.

Applicants have amended Claim 25 to additionally recite the Gag, Env and Bel2 of the viral sequences. This amendment is supported at page 6 of the specification where it is mentioned that regarding a replication-competent vector the heterologous sequences can be inserted into the Gag, Env and Bel2.

The Examiner has acknowledged that the clone pFeFV-7 of the application was not obvious in view of the prior art and has indicated that claim 8 drawn to such clone is allowable (see page 3 of the Final Action).

Claims 1-3, 5-7, 9-12 and 17-41 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Winkler et al. and Ter Meulen et al. In view of the amendments to the claims and the following remarks Applicants request that the Examiner reconsider and withdraw the rejection.

The Examiner has acknowledged that the clone pFeFV-7 of the application was not obvious in view of the prior art and in clone pFeFV-7, the FFV env gene from Winkler et al. was replaced by novel FFV env sequences (from nt positions 5118 to 10137) generated by reverse transcription PCR of viral RNAs. Such a high-titer viral vector is an absolute prerequisite for making replication-

competent as well as replication-defective vectors according to the invention (see ter Meulen, in particular the paragraph overlapping columns 7 and 8).

The amended claims now define retroviral vectors generated from the pFeFV-7 clone. The Examiner has acknowledged that pFeFV-7 was not obvious from the prior art, and therefore claimed vectors derived from pFeFV-7 are also non-obvious.

Claim 1 as amended refers to a vector comprising a first DNA sequence derived from pFeFV-7, a second DNA sequence permitting the propagation in bacteria and a desired expressible foreign DNA sequence. Winkler et al. fails to teach or suggest a clone capable of transducing a foreign gene, i.e. a clone suitable as a vector, and therefore fails to render the current claims obvious.

Applicants have amended Claims 25 to 38 such that they recite replication-competent vectors wherein the viral first DNA sequence comprises at least the 5'LTR, gag, env, bel2 and 3'LTR of pFeFV-7. Such a DNA comprises the FFV env sequences not taught or suggested by Winkler et al. or ter Meulen and, therefore, is not obvious in view of these references.

Regarding the Examiner's assertion that "Zemba et al. uses the clones of Winkler et al. and they were infectious" Applicants note that Zemba et al. teach the production of clones having "only a low level of infectivity" (page 151, column 1, full paragraph) by making further amplicons for the DNA sequences from nt positions 5118 to 9057 (see Zemba et al. page 154, last paragraph). Hence, Zemba et al. clearly teach that they did NOT obtain the full-length clones having a low level of infectivity entirely from the DNA of the clones of Winkler. The clones and DNA sequence from Winkler were defective and the DNA sequences from positions 5118 to 9057 had to be newly amplified to obtain these full-length clones "having a low level of infectivity". Therefore, Zemba et al. show that the clones and DNA sequence of Winkler et al. would not have enabled a skilled person to make an infectious full-length clone of a feline foamy virus, because

Zemba et al. indicate that an assembly of the pre-existing viral sequences from Winkler et al. would not have resulted in an infectious viral clone.

On the other hand, ter Meulen et al. clearly teach that an infectious viral clone is a prerequisite for making a retroviral vector from which self-replicating, replication competent and replication-defective vectors can be derived (see in particular the paragraph overlapping columns 7 and 8 of ter Meulen et al.). Because DNA sequences and clones from Winkler et al. do not provide a reasonable expectation of success to make an infectious full-length clone, the claimed subject-matter was not obvious in view of Winkler et al. alone or in combination with ter Meulen. Further, the claimed subject-matter was not obvious because the prior art fails to teach a process for making an infectious clone, which is a prerequisite of the claimed vectors (e.g. *In re Hoeksema*, 399 F.2d 269, 274-75, 158 USPQ 597, 601 (CCPA 1968)).

Regarding the statement that not all the claims require an infectious clone it has to be noted that ter Meulen teach that an infectious clone is also a prerequisite for obtaining a replication-incompetent vector, i.e. replication-defective vector (see, e.g, col. 8, lines 34-38 of ter Meulen). Also for replication-deficient vectors, a fully functional env gene for the construction of the required env packaging construct is absolutely needed, such functional env gene is not provided by the DNA of Winkler. Therefore, Winkler et al. also fails to render obvious non-infectious, replication-defective vectors, because it is not known in the art how to make a non-infectious, replication-defective vector without the intermediate of a fully-infectious viral clone such as pFeFV-7.


If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and

please charge any deficiency in fees or credit any overpayments to Deposit
Account No. 05-1323 (Docket # 104052.B270022).

Respectfully submitted,

March 3, 2009


Mary Anne Schofield
Registration No. 36,669

CROWELL & MORING, LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
TSR:MHN
7293447